UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,937	02/18/2004	Tracee Eidenschink	1001.2262101	1924

28075 7590 05/11/2010

CROMPTON, SEAGER & TUFTE, LLC
1221 NICOLLET AVENUE
SUITE 800
MINNEAPOLIS, MN 55403-2420

EXAMINER	
BUI, VY Q	
ART UNIT	**PAPER NUMBER**
3773	

MAIL DATE	DELIVERY MODE
05/11/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/780,937	EIDENSCHINK ET AL.	
	Examiner	Art Unit	
	Vy Q. Bui	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *11-16,19,21-24 and 34-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,17,18,20 and 25-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of invention of species 2 shown in F 11 in the reply filed on 12/12/2008 is acknowledged. The restriction is proper and is made final.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

I. Claims 1-8, 17-18, 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Bleam et al-6,143,016.

As to claims 1-8, 17-18, 29-30, Bleam-'016 (F 1-12; C 5, L 24-58) discloses balloon catheter 14/94 comprising catheter shaft 15/94, balloon 22, 1st rotatable sheath 34 of an expandable elastomer (C 5, L 38-43), balloon catheter 14/94 as 1st guidewire housing having lumen 24 for receiving 1st guidewire 26 (F 1 and F 11-12A, for example) and stents 12, 12a, 12b and 12c (F 13) disposed over 1st rotatable sheath 34 substantially as recited in the claims.

Please notice that:

1. Bleam-'016 (F 11-12A) shows element 36 of a PEEK or ABS or PVC plastic, or a flexible metal, 1st rotatable sheath 34 of an expandable elastomer (C 5, L 38-43) substantially shorter than catheter shaft 94.

2. Cylindrical surface contacting catheter shaft 15/94 is an outer surface of 1st rotatable sheath 34 in comparison to an inner surface one can create by transversally cutting 1st rotatable sheath 34, for example. Or one can consider the proximal annular surface

perpendicular to the longitudinal axis of 1st rotatable sheath 34 as inner surface and other surfaces of 1st rotatable sheath 34 as outer surfaces.

3. 1st stent 12 (F 7-9, for example) is disposed about at least a portion of the 1st rotatable sheath 34 and at least a portion of the 1st guidewire housing 14 or 94 / balloon 22 because 1st stent 12 overlays over both 1st rotatable sheath 34 and 1st guidewire housing 14/ 94 / balloon 22.

4. 1st rotatable sheath 34 is rotatable about a portion of the catheter shaft 15/94 because 1st rotatable sheath 34 is bendalbe about a portion of the catheter shaft 15/94.

II. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Vardi et al-6,692,483.

As to claim 1, Vardi-'483 (F 1-9) balloon catheter 12 comprising catheter shaft 12, 1st expandable rotatable sheath / balloon 11, 1st guidewire housing 14 having a lumen for receiving 1st guidewire 31 (F 5, for example) and 1st stents 25 (F 7A) disposed over 1st rotatable sheath 11 and 1st guidewire housing 14, and 2nd stent 40 substantially as recited in the claim. Notice that balloon 11 can be reasonably considered as a sheath covering a distal portion of catheter shaft 12.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 9-10, 20, 25-28, 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bleam et al-6,143,016.

1. As to claims 9-10, Bleam-'016 discloses substantially the claimed invention,

except for diameter of the stent in a collapsed stent state at the proximal end region is either smaller than a diameter at a body portion, or tapered. It would have been obvious to one of ordinary skill in the art to provide the stent with either reduced diameter or tapered diameter at the proximal end of the stent in the collapsed state as recited in the claims as this configuration would prevent the proximal end of the stent to injure a blood vessel wall during deployment of the stent, especially during proximally motion of the stent delivery catheter. Further, it would have been an obvious matter of design choice to have the proximal end region of the stent in the collapsed state as recited in the claims, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

Alternatively, claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bleam et al-6,143,016 in view of Girton et al.-6,997,946 B2. As to claims 9-10, Bleam-'016 discloses substantially the claimed invention, except for diameter of the stent in a collapsed stent state at the proximal end region is either smaller than a diameter at a body portion, or tapered. However, Girton-'946 (F 3, 5C, 8-9; C 4, L 48-55) discloses tapered proximal end portions 18 of stent 10 for enhance securement of the stent to a balloon during the stent deployment. It would have been obvious to one of ordinary skill in the art to provide the stent with either reduced diameter or tapered diameter at the proximal end of the stent in the collapsed state as recited in the claims as this configuration would enhance securement of the stent to a balloon during the stent deployment.

2. As to claims 20, 25, Bleam-'016 discloses substantially the claimed invention, except for different therapeutic agents for a local treatment of a blood vessel. However, the therapeutic materials are well known for treatment a blood vessel. It would have been obvious

to one of ordinary skill in the art to provide a therapeutic agent as recited in the claims as these agents are well known for treatment a blood vessel.

Alternatively, claims 20, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bleam et al-6,143,016 in view of Buigre et al.-6,391,052 B2. As to claims 20, 25, Bleam-'016 discloses substantially the claimed invention, except for a therapeutic agent, such as a collagen, or a heparin for a local treatment of a blood vessel. However, the therapeutic coating of collagen or heparin on a stent for a treatment a blood vessel is well known. For example, Buigre-'052 (C 1, L 15-20; C2, L 46-61), discloses coating a stent with a collagen and heparin for a treatment of a blood vessel. In view of Buigre-'052, it would have been obvious to one of ordinary skill in the art to provide a Bleam-'016 stent with collagen and heparin for treatment a blood vessel.

3. As to claims 26-28, Bleam-'016 discloses substantially the claimed invention, except for a lubricious coating, a hydrophilic coating or a tecophilic coating. However, these coating are well known to use for a catheter device to lubricate the catheter and facilitate the deployment of a catheter in a blood vessel. It would have been obvious to one of ordinary skill in the art to provide a lubricious coating, a hydrophilic coating or a tecophilic coating as recited in the claims as these coatings are well known for use with a catheter to facilitate a deployment of the catheter in a blood vessel.

Alternaitvely, claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bleam et al-6,143,016 in view of Trogolo et al.-6,296,863 B2. As to claims 26-28, Bleam-'016 discloses substantially the claimed invention, except for a material as recited in the claims. However, these materials are well known lubricious and hydrophilic material suitable for use inside a human body. For example, Trogolo-'863 (C 3, L 11-22) discloses that tecophilic is a hydrophilic material suitable for coating an implant used inside a human body. It would have

been obvious to one of ordinary skill in the art to provide a lubricious, hydrophilic coating, such as a tecophilic coating as taught by Trogolo-'863, to a device as recited in the claims as this materials is suitable for use in a human body.

4. Claims 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bleam et al-6,143,016 in view of Suzuki et al.-US20050027248A1 (JP-2003-202958).

As to claims 31-33, Bleam-'016 discloses substantially the claimed invention, except for a polymeric matrix, such as a elastomeric polyamide matrix and reinforcing polyamide. However, Suzuki-'248 (section [0035]) discloses an expandable balloon layer comprising a polyamide elastomer-based matrix and a polyamide as recited in the claims for making the balloon expandable and durable to an inflation pressure. In view of Suzuki-'248, it would have been obvious to one of ordinary skill in the art to modify the 1st rotatable sheath 34 to comprise a polyamide elastomer-based matrix and a polyamide as recited in the claims for making the sheath expandable and durable to an inflation pressure.

Response to Arguments

Applicant's arguments filed 2/20/2010 have been fully considered but they are not persuasive.

The applicant (Remarks, page 15/17) argued that "As such, the sheath 28 of Bleam et al. does not appear to have a length substantially less than that of the catheter shaft 15. Thus, nothing in Bleam et al. appear to disclose "the first rotatable sheath having a length substantially less than that of the catheter shaft", as recited in claim 1.

However, as indicated in the above 102(b) rejection of claim 1, Bleam et al. (F 11-12) clearly shows 1st rotatable sheath 34 substantially shorter than catheter shaft 94 as recited in claim 1.

The amendment of claim 1 further defines the present invention. However, claim 1 is still broad enough to read on the Bleam et al. device as indicated in the above 102(b) rejection of claim 1.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 571-272-4692. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vy Q. Bui/
Primary Examiner, Art Unit 3773